REMARKS

The following remarks are made in response to the Office Action mailed October 31, 2003. Claims 1-21 and 40-47 have been withdrawn from consideration. No claims have been cancelled. Claims 22-39 and 53-58 were rejected. With this Response, claims 22-24, 27-39, 49, 51, 53, and 57-58 have been amended. Claims 22- 39 and 48-58 remain pending in the application and are presented for reconsideration and allowance.

Claim Rejections under 35 U.S.C. § 112

In the Office Action, claim 52 was rejected under 35 U.S.C. § 112, second paragraph as being indefinite.

Claim 52 as presently presented specifies that the data network interface is adapated to be removably coupled to patient monitoring sensors.

Given the language in the Office Action directed to claim limitations of "derived from at least one of", it appears that this current rejection is an inadvertent repeat of an earlier rejection made in an Office Action mailed on June 24, 2003.

Claim 52 as presently presented contains none of the language identified in the rejection. Claim 52 was amended into its present form in an Amendment filed August 27, 2003. This Amendment was acknowledged and entered in the Advisory Action mailed September 9, 2003, which stated that "the claim amendments filed and entered appear to cure claim objections and 112 issues." The current Office Action affirms entry of Applicant's Amendment filed September 24, 2003, which includes claim 52 in its present form.

For these reasons, this rejection under 35 U.S.C. 112 appears to be moot and Applicant respectfully requests withdrawal of the rejection.

Claim Rejections under 35 U.S.C. § 102

In the Office Action, claims 22-39 were rejected under 35 U.S.C. § 102(e) as being anticipated by Liff U.S. Patent 6, 471, 089 (herein "Liff").

A. Independent Claim 22

Applicant's independent claim 22 specifies an intelligent drug dispensing appliance comprising a controller, a reservoir of unpackaged pharmaceutical, a drug delivery mechanism, and a data network interface coupled to said controller. The reservoir is

configured to contain a plurality of individual unit doses of unpackaged pharmaceutical that is specific to an individual patient and to be dispensed over time to the individual patient. The unpackaged pharmaceutical includes at least one of individual tablets, liquids, or gasses, to be administered to the individual patient as individual unit doses for direct use by the patient according to a treatment regimen. The drug delivery mechanism is, coupled to, and responsive to the controller and to the reservoir, to controllably dispense the unpackaged pharmaceutical directly from the reservoir to the individual patient in a precise amount corresponding to the individual unit dose in response to signals from said controller. The intelligent drug dispensing appliance is sized and shaped for non-hospital placement proximate to the individual patient.

Liff is directed to an automated apparatus for dispensing packaged pharmaceuticals. The apparatus includes a cabinet housing for storing a variety of packaged pharmaceuticals in a plurality of bins. Each bin stores a particular variety of packaged pharmaceuticals where each package typically contains a plurality of unit doses. See Liff at Column 2, lines 19-27. The bins are vertically-disposed columns shaped to store a plurality of bottles stacked vertically and each bottle is sealed and contains a selected number of doses. See Liff at Column 2, lines 51-54; see also Column 6, line 2 and lines 30-33; see also Column 12, lines 53-68.

First, in contrast, Applicant's claimed intelligent drug dispensing appliance has a reservoir configured to contain a plurality of individual unit doses of unpackaged pharmaceuticals (e.g., together within the reservoir). Liff fails to disclose dispensing unpackaged pharmaceutical from a reservoir, as claimed by Applicant. Instead, Liff dispenses bottles, i.e. packaged pharmaceuticals rather than individual doses free from packaging directly from a reservoir, as claimed by Applicant.

Second, Applicant's claimed appliance specifies that the reservoir of unpackaged pharamaceutical is specific to an individual patient – not a doctor, nurse, pharmacist, clinic or hospital.

Third, in contrast to Liff, Applicant's claimed appliance specifies a drug delivery mechanism that controllably dispenses the unpackaged pharmaceutical directly from the reservoir to the individual patient. Liff fails to disclose dispensing unpackaged

pharmaceuticals from its cabinet and instead Liff dispenses bottles, i.e., packaged pharamaceuticals.

Fourth, Applicant's claimed intelligent drug dispensing appliance is sized and shaped for non-hospital placement proximate to the individual patient. In contrast, Liff as shown in Figures 1,3 discloses vending machine-style cabinet 20 hold dozens of bottles and clearly is not sized or adapted for use by an individual patient, as contemplated by Applicant's claimed invention.

Fifth, Liff teaches away from "unit-dose dispensing for individual patients" as being unsuitable for filling weekly/monthly prescriptions – to which Liff is addressed. See Liff, Column 2, lines 4-6. Moreover, Liff limits dose-dispensing to the context of hospital-based systems of drug distribution. See Liff Column 1, lines 37-68, Column 2, lines 1-5. Finally, this backround description in Liff regarding hospital-type systems is quite brief and fails to address the limitations of Applicant's claimed intelligent drug dispensing appliance regarding the structure or purpose of a reservoir, whether or not the pharmaceutical is packaged or not, etc., the size/shape of the appliance for non-hospital placement.

For these reasons, Applicant's independent claim 1 is allowable over Liff.

Applicant's limitations directed to a reservoir configured to contain a plurality of doses of unpackaged pharmaceutical are supported in the specification in several ways. First, Applicant's intelligent drug appliance contains a reservoir and a gate or valve, with the gate or valve enabling dispensing of a precise amount of pharmaceutical. Reservoir 104 contains a supply of substances such as liquids, tablets, gasses for a treatment regimen. Applicant's specification page 2, lines 15-19. The appliance tracks depletion of the pharamaceutical in reservoir 104 (see Applicant's specification page 2, lines 29-31; page 4, lines 12-23; page 4, lines 26-32; page 5, lines 1-24) in contemplation of dispensing multiple doses over time, as part of the treatment regimen, where reservoir 104 holds doses which are dispensed directly from reservoir 104 to the patient. Accordingly, Applicant's specification contains no mention of bottles or packages of pharmaceuticals for grouping multiple doses together as Applicant's intelligent drug dispensing appliance is directed toward direct dispensing of tablets, liquids, gasses from its reservoir via a drug dispensing mechanism.

As described in Applicant's specification, this intelligent drug dispensing appliance also comprises a pharmaceutical level detector which determines the relative amount of

pharmaceutical in the reservoir. Several embodiments of detecting the level are described (e.g., depth measurement, static pressure, measured weigh – page 5, lines 9-24), each of which would be impaired were the pharmaceutical "packaged" as multiple doses, as in Liff. In addition, the reservoir can hold liquids or gasses, both of which fill up the reservoir and "flow" out of reservoir, such as via gate/valve 108. This feature of "flowing" clearly comports with unpackaged tablets, liquid, gasses in contrast to the packages of Liff, such as bottles, which roll, tumble, or slide from cabinet 20. Bottles/packages in Liff would clearly inhibit detection of impending depletion of a pharmaceutical from a reservoir to enable an automated prescription refill into/for reservoir 104, as would be relevant for Applicant's appliance holding unpackaged pharmaceuticals.

Accordingly, Liff fails to anticipate or make obvious Applicant's claimed intelligent drug dispensing appliance of claim 22. Therefore, Applicant respectfully submits that independent claim 1 is allowable over Liff, and believes that claims 23-30 and claims 48-52 are allowable over Liff based upon their dependency from independent claim 22.

B. Independent Claim 31 and 32

Applicant's independent claim 31 specifies an intelligent drug dispensing system providing replenishment of pharmaceutical medication. The system comprises an intelligent drug dispensing appliance and a pharmaceutical replenishment request data server in communication with to the data network interface to receive medication replenishment request signals from at least one intelligent drug dispensing appliance. The intelligent drug dispensing appliance includes a data network interface through which pharmaceutical replenishment request signals can be sent from the intelligent drug dispensing appliance, a controller and a reservoir. The reservoir is configured to contain a plurality of individual unit doses of unpackaged pharmaceutical to be dispensed directly to an individual patient, the pharmaceutical including at least one of individual tablets, liquids, and gasses, to be administered as individual unit doses according to a treatment regimen for direct use by the patient. The intelligent drug dispensing appliance is sized and shaped for placement proximate to the patient at a non-hospital location.

Applicant's independent claim 32 specifies an intelligent drug dispensing system providing replenishment of pharmaceutical medication. The system comprises an intelligent

drug dispensing appliance and a pharmaceutical replenishment request data server in communication with the data network interface to send medication replenishment request signals to at least one intelligent drug dispensing appliance. The intelligent drug dispensing appliance includes a data network interface through which pharmaceutical replenishment request signals can be received from the intelligent drug dispensing appliance, a controller and a reservoir. The reservoir is configured to contain an aggregated plurality of individual unit doses of unpackaged pharmaceutical to be dispensed directly to an individual patient, the pharmaceutical including at least one of individual tablets, liquids, and gasses, to be administered as individual unit doses according to a treatment regimen for direct use by the patient. The intelligent drug dispensing appliance is sized and shaped for placement proximate to the patient at a non-hospital location.

For the reasons described in **Section A** regarding independent claim 22, Liff fails to disclose Applicant's independent claims 31 and 32 of an intelligent drug dispensing system that includes a reservoir that is configured to contain a plurality of individual unit doses of unpackaged pharmaceutical to be dispensed directly to an individual patient, the pharmaceutical including at least one of individual tablets, liquids, and gasses, to be administered as individual unit doses according to a treatment regimen for direct use by the patient.

Also for the reasons described in **Section A** regarding independent claim 22, Liff also fails to disclose the intelligent drug dispensing appliance of independent claims 31 and 32 being sized and shaped for placement proximate to the patient at a non-hospital location.

Accordingly, Applicant respectfully submits that independent claims 31 and 32 are allowable over Liff. In addition, claims 33-35 are likewise believed to be allowable based on their dependency from independent claims 31 and 32.

C. Applicant's Independent Claim 36

Applicant's independent claim 36 specifies an intelligent drug dispensing system providing automatic replenishment of pharmaceuticals. The system comprises a pharmaceutical replenishment request data server operatively coupled to a data network so as to receive pharmaceutical replenishment request messages from at least one intelligent drug dispensing appliance. The at least one intelligent drug dispensing apparatus includes a

controller and a reservoir of a plurality of individual unit doses of unpackaged pharmaceutical to be dispensed over time directly to an individual patient in a plurality of discrete individual unit doses according to a treatment regimen for direct use by the patient. The at least one intelligent drug dispensing apparatus is sized and shaped for placement proximate to the patient at a non-hospital location.

For the reasons described in **Section A** regarding independent claim 22, Liff fails to disclose Applicant's independent claim 36 of an intelligent drug dispensing system that includes at least one intelligent drug dispensing apparatus including a controller and a reservoir of a plurality of individual unit doses of unpackaged pharmaceutical to be dispensed over time directly to an individual patient in a plurality of discrete individual unit doses according to a treatment regimen for direct use by the patient.

Also for the reasons described in **Section A** regarding independent claim 22, Liff also fails to disclose Applicant's at least one intelligent drug dispensing apparatus of independent claim 36 being sized and shaped for placement proximate to the patient at a non-hospital location.

Accordingly, Applicant respectfully submits that independent claim 36 is allowable over Liff. In addition, claims 37-39 are likewise believed to be allowable based on their dependency from independent claim 36.

D. Applicant's Independent Claim 53

Claims 53 and 56 were rejected under 35 U.S.C. § 102(e) as being anticipated by Shusterman U.S. Patent 6,471,087 (herein "Shusterman").

Applicant's independent claim 53 specifies an intelligent drug dispensing appliance comprising a controller, a reservoir, a drug dispensing mechanism, pharmaceutical depletion guard, and a data network interface coupled to the controller. The reservoir is configured to contain a supply of unpackaged pharmaceutical specific to the individual patient to be dispensed over time, the supply including a grouped plurality of individual unit doses (i.e., individual unit doses grouped together within the reservoir).

The drug dispensing mechanism is coupled to, and responsive to, the controller and to the reservoir to dispense the unpackaged pharmaceutical directly to the individual patient from the reservoir in a precise amount in response to signals from said controller. The

pharmaceutical depletion guard includes a pharmaceutical level detector coupled to the controller and the data network interface, wherein the data network interface is capable of sending a message to at least one of a health care provider or pharmaceutical supplier, the data message from the data network interface including at least one of a value of a measured amount of unpackaged pharmaceutical in the reservoir patient identity, a pharmaceutical identity, and a treatment regimen. The intelligent drug dispensing appliance is sized and shaped for placement proximate to the individual patient remote from a hospital location.

For the reasons described in **Section A** regarding independent claim 53, Shusterman fails to disclose Applicant's independent claim 53 of an intelligent drug dispensing appliance that includes a reservoir that is configured to contain a supply of unpackaged pharmaceutical to be dispensed over time to the individual patient, the supply including a grouped plurality of individual unit doses (i.e., individual unit doses grouped together within the reservoir).

Instead, Shusterman discloses a compartmentalized carousel in which individual unit doses are separated from each other into different compartments and are not grouped together within a reservoir, as claimed by Applicant.

In addition, Shusterman fails to disclose Applicant's claimed intelligent drug dispensing appliance including a pharmaceutical depletion guard including a pharmaceutical level detector coupled to the controller and the data network interface, wherein the data network interface is capable of sending a message to at least one of a health care provider or pharmaceutical supplier, the data message from the data network interface including at least one of a value of a measured amount of unpackaged pharmaceutical in the reservoir patient identity, a pharmaceutical identity, and a treatment regimen.

Accordingly, Applicant respectfully submits that independent claim 53 is allowable over Shusterman. In addition, claims 53-58 are likewise believed to be allowable based on their dependency from independent claim 53.

Claim Rejections under 35 U.S.C. § 103

A. Applicant's Dependent Claim 49

In the Office Action, claim 49 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Liff in view of Monkhouse U.S. Patent 6,514,518 (herein "Monkhouse"). Claim 49 depends from independent claim 22 and dependent claim 48. Claim 48 further specifies the unpackaged pharmaceutical is at least one liquid material and claim 49, depending from claim 48, specifies that the drug delivery mechanism includes an ink-jet print head configured to directly dispense the individual unit doses of precise amounts of the liquid from the reservoir to the individual patient.

Since independent claim 22 is believed to be patentable over Liff for the reasons discussed above, dependent claim 49 is also believed to be allowable based on its dependency from independent claim 22, via intervening claim 48.

In addition, claim 49 is allowable over Liff and Monkhouse because Liff fails to disclose an ink-jet head as a drug dispensing mechanism and because Monkhouse fails to disclose **dispensing** an unpackaged pharmaceutical directly the individual patient from a reservoir to the patient, as claimed by Applicant.

Instead, Monkhouse is limited to using an ink-jet head to build a solid dosage form, such as an implant. Only after being built via three-dimensional printing (3DP), the dosage form is then dispensed to the patient, such as by implanting the solid dosage form into the patient. See Monkhouse Column 2, lines 10-24; Column 3, lines 7-8, lines 41-45, lines Accordingly, the ink-jet head in Monkhouse is not associated with directly dispensing a liquid pharamaceutical to a patient – its only associated with building a solid pharamaceutical for later dispensation as an implant. See Monkhouse at Column 4, lines 44-48 (e.g., "printhead 22 deposits fluid 24 onto the powder layer .... And the process is repeated until the dosage forms are completed"). Moreover, there is no suggestion or motivation in either Liff or Monkhouse to modify the system of Liff, to modify the system of Monkhouse, much less combine Liff and Monkhouse to achieve Applicant's claimed system.

For these reasons, claim 49 is not made obvious by Liff and/or Monkhouse and therefore claim 49 is believed to be allowable over Liff and/or Monkhouse.

B. Applicant's Dependent Claim 52

In the Office Action, claim 52 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Liff in view of O'Brien U.S. Patent 5,963,136 (herein "O'Brien").

Claim 52 depends from claim 51 and specifies that the data network interface is adapted to be removably coupled to the patient monitoring sensors.

Since independent claim 22 is believed to be patentable over Liff for the reasons discussed above, dependent claim 52 is also believed to be allowable based on its dependency from independent claim 22, via intervening claims 48-51.

CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 22-39 and 49-58 are in form for allowance and are not taught or suggested by the cited references. No new matter has been believed to be added and Applicant believes that prosecution of this case has been advanced to a point of successful conclusion. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 22-39 and 49-58 are respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 08-2025.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to either W. Bradley Haymond at Telephone No. (541) 715-01569, Facsimile No. (541) 715-8581 or Paul S. Grunzweig at Telephone No. (612) 767-2504, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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CERTIFICATE UNDER 37 C.F.R. 1.8: The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope address to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 21st day of June, 2004.

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